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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,534	07/23/2003	Lloyd Wolfinbarger JR.	64230-00004USD1	6665

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BAKER & MCKENZIE LLP  
Pennzoil Place, South Tower  
711 Louisiana, Suite 3400  
HOUSTON, TX 77002-2716

EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/624,534	WOLFENBARGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58,60-65,70,71,73-76,78,80,86-90,93,96-99 and 102-132 is/are pending in the application.
- 4a) Of the above claim(s) 1-55,93,103-107 and 110-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-58,60-65,70,71,73-76,78,80,86-90,96-99,102,108,109,121 and 132 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/23/06</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1651

**DETAILED ACTION**

Claims 1-58, 60-65, 70, 71, 73-76, 78, 80, 86-90, 93, 96-99, 102-132 are pending. Claims 56-58, 60-65, 70, 71, 73-76, 78, 80, 86-90, 96-99, 102, 108, 109, 121-132 are considered on the merits. Claims 1-55, 93, 103-107, 110-120 are withdrawn from consideration as being drawn to a non-elected invention. The election was without traverse.

***Specification***

The disclosure is objected to because of the following informalities:

The status of the parent 09/528,371 should be updated and the first paragraph corrected to reflect that the instant application is a divisional of 09/528,371 now US 6,734,018 which is a CIP of 09/327240, now abandoned.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or

Art Unit: 1651

patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 56-58, 60-65, 70, 71, 73-76, 78, 80, 86-90, 96-99, 102, 108, 109, 121-132 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-56 of U.S. Patent No. 6,734,018. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are coextensive and overlapping in scope.

***Claim Rejections – 35 USC § 112***

**INDEFINITE**

Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim states that the extracting solution is reactive with said anionic detergent, but fails to stipulate what reaction occurs with what component of the extracting solution. It is considered that any solution is reactive with an anionic detergent because the detergent disassociates in water.

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1651

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56–58, 60–62, 64, 86–90, 96–99, 102, 108, 109, 121–132 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,776,853 [AV].

The claims are directed to a method for producing an acellular soft tissue implant comprising:

- extracting the tissue with a hypotonic buffer containing a nonionic detergent and an endonuclease,
- treating the extracted tissue with an anionic detergent,
- washing the tissue .

US 4,776,853 teaches a method of producing an acellular soft tissue implant comprising:

- extracting the tissue with hypotonic buffer at an alkaline pH,
- treating the tissue with a buffered solution which is hypertonic and contains nonionic detergent,
- washing the tissue,
- treating the tissue with a buffered solution containing a nuclease,
- extracting the tissue with an anionic detergent at alkaline pH,
- washing the tissue,
- storing the tissue in isotonic solution containing antibiotics (col. 3, ls. 26–65).

The reference teaches the use of both hypotonic and hypertonic conditions as well as both nonionic and ionic detergents and nuclease treatment to hydrolyze both RNA and DNA.

The order of the addition of the treating conditions to the tissue appears to be different from the claimed method, particularly where the first extraction solution is hypotonic and also contains the nonionic detergent and the endonuclease.

Art Unit: 1651

However, please note that the order of adding ingredients or treating agents is considered to be *prima facie* obvious in the absence of evidence to the contrary, see MPEP 2144.04 IV. C.

Further, concentrations, to the extent that they differ from the concentrations disclosed in the prior art, are considered to be routine optimization in the absence of evidence to the contrary.

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,776,853 [AV] as applied to claims 56–58, 60–62, 64, 86–90, 96–99, 102, 108, 109, 121–132 above, and further in view of US 5,531,791 [A].

Claim 63 is directed to the storage of the processed tissue in ultrapure, endotoxin-free water, while the primary reference is silent with regard to the purity of the water used to make the storage buffer, endotoxin-free, ultrapure water has been routinely used in the field of transplantation/implantation as shown in US 5,531,791 (col. 8, l. 60).

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,776,853 [AV] as applied to the claims 56–58, 60–62, 64, 86–90, 96–99, 102, 108, 109, 121–132 above, and further in view of US 5,357,636 [B].

Claim 65 is drawn to the type of decontaminating agent used in the storage solution, namely various alcohols, chlorine dioxide, methylparaben.

US 5,357,636 teaches that antimicrobial agents are antibiotics, alcohols, chlorine dioxide, methylparaben, etc. (cols. 27 and 28). Thus, the substitution of an antimicrobial agent such as an alcohol, chlorine dioxide etc., for antibiotics in the storage solution would be obvious. This is considered to a substitution of equivalents in the absence of evidence to the contrary.

Claims 70, 71, 73–75, 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,776,853 [AV] as applied to the claims 56–58, 60–62,

Art Unit: 1651

64, 86-90, 96-99, 102, 108, 109, 121-132 above, and further in view of Moreno *et al.* [U].

The primary reference teaches the use of both DNAase and RNAase to treat the tissue (col. 6, l. 38). However, it lacks the teaching of using a single enzyme which has both DNAase and RNAase activity.

Moreno *et al.* describe a genetically engineered nuclease which hydrolyzes both DNA and RNA. It has highest activity at pH 8, [Mg<sup>2+</sup>] 2mM, see abstract.

The substitution of an enzyme which has both RNAase and DNAase activity as taught by Moreno *et al.* for the two separate enzymes each of which have a single activity in the process of US 4,776,853 would have been obvious because it would be a substitution of equivalents since the activity and the degradation of the target compounds (RNA and DNA) would be the same or so similar as to be indistinguishable in the absence of evidence to the contrary. Inclusion of magnesium chloride in the solution would be obvious because the enzyme of Moreno *et al.* requires it for activity.

Claims 76, 78, 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,776,853 [AV] as applied to the claims 56-58, 60-62, 64, 86-90, 96-99, 102, 108, 109, 121-132 above, and further in view of US 5,095,925 [C].

US 5,095,925 discloses a closed system for the preparation of allograft tissue which uses a pressure mediated flow (col. 3, l. 45). The liquids to be flowed are not limited, but may contain, for example, a surfactant (claim 4).

The use of a pressure mediated flow of solutions for treatment of a tissue being processed for transplantation instead of the stirring and rocking as described in the method of US 4,776,853 would have been obvious when taken

Art Unit: 1651

with US 5,095,925 which discloses use of pressure mediated flow to introduce solutions to tissue for use in transplantation.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a large, stylized initial 'S' and a horizontal line extending to the right.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
July 27, 2006